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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/627,372	07/24/2003	Harrihar A. Pershadsingh	421842000400	2447
25226	7590	01/26/2005	EXAMINER	
MORRISON & FOERSTER LLP			WEDDINGTON, KEVIN E	
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1614

DATE MAILED: 01/26/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

10/627,372

Applicant(s)

PERSHADSINGH, HARRIHAR A.

Examiner

Kevin E. Weddington

Art Unit

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 September 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) 16 and 17 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

Claims 1-17 are presented for examination.

Applicant's information disclosure statements filed November 24, 2003; May 24, 2004 and August 6, 2004 have been received and entered.

Applicant's election filed September 7, 2004 in response to the restriction requirement of August 5, 2004 has been received and entered. The applicant elected the invention described in claims 1-15 (Group I) without traverse.

Claims 16 and 17 are withdrawn from consideration as being drawn to the non-elected invention (37 CFR 1.142(b)).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-15 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 58-87 of copending Application No. 10/801,437. Although the conflicting claims are not identical, they are not patentably distinct from each other because the present application

Art Unit: 1614

teaches a method for treating or prophylactically preventing an inflammatory or metabolic disorder in a mammal by administering to the mammal in need thereof, a therapeutically effective amount of a compound sufficient to (a) at least partially activate peroxisome proliferator activated receptors (PPARs) and (b) at least partially inhibit, antagonize or block an activity of angiotensin II type 1 receptors; and the copending application teaches a method for treating or preventing an inflammatory or metabolic disorder in a mammal comprising administering to the mammal in need thereof, a therapeutically effective amount of a compound sufficient to at least partially activate a peroxisome proliferator-activated receptor (PPAR). The claims of the copending application 10/801,437 teaches the limitations of the claims of the present application since the instant compound known to at least partially activate a (PPAR) would inherently at least partially inhibit, antagonize or block an activity of angiotensin II type 1 receptor and is the only compound(s) known to possess the said two steps mechanisms as suggested by the applicant's specification of copending application 10/801,437 on page 2, paragraph **0005**.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-15 are not allowed.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

Art Unit: 1614

art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-15 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating type 2-diabetes, metabolic syndrome and inflammation caused by osteoarthritis with telmisartan, does not reasonably provide enablement for treating all inflammatory or metabolic disorders or prophylactically preventing an inflammatory or metabolic disorder by administering all compounds sufficient to at least partially activate peroxisome proliferator activated receptors (PPARs) and at least partially inhibit, antagonize or block an activity of angiotensin II type 1 receptors. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

In this regard, the application disclosure and claims have been compared per factors indicated in the decision In re Wands, 8 USPQ2d 1400 (Fed. Cir. 1988) as to undue experimentation.

The factors include:

- 1) the quantity of experimentation necessary
- 2) the amount of direction or guidance provided
- 3) the presence or absence of working examples
- 4) the nature of the invention
- 5) the state of the art
- 6) the relative skill of those in the art

Art Unit: 1614

7) the predictability of the art and

8) the breadth of the claims.

The instant specification fails to provide guidance that would allow the skilled artisan background sufficient to practice the instant invention without resorting to undue experimentation in view of further discussion below.

The nature of the invention, state of the prior art, relative skill of those in the art and the predictability of the art

The claimed invention relates to treating or prophylactically preventing inflammatory or metabolic disorders.

The relative skill of those in the art is generally that of a PH.D. or M.D.

There are no known preventive therapies for all inflammatory disorders or all metabolic disorders in the art.

It is clear the art to which the present invention relates is highly unpredictable and unreliable with respect to conclusions drawn from laboratory data extrapolated to clinical efficacy.

The amount of direction or guidance provided and the presence or absence of working examples

There are no working examples showing compounds sufficient (a) at least partially activate peroxisome proliferator activated receptors (PPARs) and (b) at least partially inhibit, antagonize or block an activity of angiotensin II type 1 receptors will, in fact, prevent all inflammatory disorders or metabolic disorders especially in a human

Art Unit: 1614

not presently at risk of or predisposed to developing such disorder. Current modes of treatment are known, but there are no known agents, which can prevent all inflammatory disorders or metabolic disorders.

The working examples shown are limited to the administration of telmisartan for treating type 2-diabetes, one specific metabolic disorder, metabolic syndrome and one specific inflammatory disorder, osteoarthritis.

The quantity of experimentation necessary

Applicant has failed to provide guidance as to which particular cause would be prevented for inflammatory or metabolic disorders. The skilled artisan would expect the interaction of a particular drug in the prevention of inflammatory disorders or metabolic disorders to be very specific and highly unpredictable absent a clear understanding of the structural and biochemical basis of the agent. The instant specification set forth no such understanding or any criteria for extrapolating beyond the administration of telmisartan and other associated compounds to treat all inflammatory disorders or metabolic disorders. Even for the data presented, no direction is provided to prevent inflammatory disorders since there are many pathways that cause inflammatory disorders or metabolic disorders and its causes. Absent reasonable *a priori* expectation of success, one skilled in the art would have to test extensively many conditions that may lead to the inflammatory disorder and metabolic disorders of claim 1 to discover which causes or pathways are prevented. Since each prospective embodiment, as well as future embodiments as the art progresses, would have to be empirically tested,

Art Unit: 1614

undue experimentation would be required to practice the invention as it is claimed in its current scope. The specification provides inadequate guidance to do otherwise.

Claims 1-15 are not allowed.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 11 and 13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 11 and 13 recite the limitation "telmisartan" and "irbesartan" in claim 11, line 1 and claim 13, line 1.

Claims 11 and 13 depend on claim 8, but the compounds "telmisartan" and "irbesartan" are not derived from this general formula of claim 8.

There is insufficient antecedent basis for this limitation in the claim.

Claims 11 and 13 are not allowed.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3-7, 13 and 14 rejected under 35 U.S.C. 102(b) as being anticipated by O'Donnell et al., "Irbesartan lowers blood pressure and ameliorates renal injury in experimental non-insulin-dependent diabetes mellitus", *Kidney International*. Vol. 52, Supplement 63, (1997), pages S218-S220.

O'Donnell et al. teach the use of irbesartan, a compound that partially activated peroxisome proliferator activated receptors (PPARs) and partially inhibit, antagonize or block an activity of angiotensin II type 1 receptor, to low blood pressure and ameliorates renal injury in experimental non-insulin-dependent diabetes mellitus (a metabolic disorder). (See the abstract) Note particularly lines 6-8 shows irbesartan was administered in the drinking water (orally) in a dosage range of 15 mg to 50 mg in which the applicants' preferred dosage range of about 20 mg to about 100 mg overlaps. As to the irbesartan increases the activity of a PPAR subtype, PPARgamma or a PPARgamma-retinoid X receptor heterodimer is inherent since a compound of identical function cannot have mutually exclusive properties. If the prior art teaches the identical compound (a compound of claim 1), the properties applicant discloses and/or claim is necessarily present. (See In re Spada, 911 F. 2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir., 1990)). Clearly, the cited reference anticipates the applicant's instant invention with every limitation, therefore, the instant invention is unpatentable.

Claims 1, 3-7, 13 and 14 are not allowed.

Claim Rejections - 35 USC § 103

Art Unit: 1614

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 8-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Naka et al. (6,100,252).

Naka et al. heterocyclic compounds that are angiotensin II type 1 receptor blockers (ARB), which can be optionally derivatized to also partially activate PPARs. Note column 41, lines 51-61 states the compounds are known to treat hypertension. Also note in column 41, lines 62-67 and column 42, lines 1-3; the compounds can be administered orally or topically.

The instant invention differs from the cited reference in that the cited reference does not teach the instant heterocyclic compounds, benzimidazoles, are used to treat inflammatory or metabolic disorders. However, one skilled would assumed the instant benzimidazoles would be effective to treat a metabolic disorders, such as metabolic syndrome or diabetes mellitus since hypertension is a complication associated with metabolic syndrome (See the enclosed THE MERCK MANUAL OF MEDICAL INFORMATION) and diabetes mellitus in the absence of evidence to the contrary.

Claims 8-10 are not allowed.

Art Unit: 1614

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kevin E. Weddington whose telephone number is (571)272-0587. The examiner can normally be reached on 11:00 am-7:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (571)272-0953. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Kevin E. Weddington
Primary Examiner
Art Unit 1614

K. Weddington
January 21, 2005